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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/887,496	06/22/2001	Partha S. Banerjee	18025-1014	7707

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EXAMINER

BAHAR, MOJDEH

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 04/24/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/887,496

Applicant(s)

BANERJEE ET AL.

Examiner

Mojdeh Bahar

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-83, 87-89, 93 and 99-121 is/are pending in the application.
- 4a) Of the above claim(s) 65-68, 93, 113-116, 120 and 121 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-64, 69-83, 87-89, 99-112 and 117-119 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>6</u> | 6) <input type="checkbox"/> Other: |

Applicant's response to the restriction requirement submitted January 31, 2002 is acknowledged.

Applicant's election therein of the invention of Group I, claims 1-83, 87-89, 99-112 and 117-119 and the species formoterol and fluticasone propionate, in Paper No. 6 submitted January 31, 2002 is acknowledged.

Applicant has traversed the restriction between Groups I and III arguing that these two groups are related as combination-subcombination. Note that the pharmaceutical composition of Group I comprises two actives (formoterol and fluticasone, for example), whereas the pharmaceutical composition of Group III comprises at the very least three actives (formoterol, an anti-inflammatory steroid and at least one more active). These two groups are distinct since they have different modes of operation. The same line of analysis is applicable to Groups II and IV, these methods are distinct from one another because the pharmaceutical compositions employed in each of the methods is distinct. Therefore Groups II and IV are also distinct due to their different mode of operation.

The restriction is still deemed proper and is made FINAL.

Claims 93, 113-116 and 120-121 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a non-elected species, there being no allowable generic or linking claim.

Claims 65-68 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to non-elected species.

Claims 1-64, 69-83, 87-89, 99-112 and 117-119 are examined on the merits herein. The claims have been examined in so far as they relate to the elected species.

Claim Objections

Claim 63 is objected to because of the following informalities: The employment of parenthetical expressions “(BMP)” and “(BDP)” is considered informal in the claim.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 63-72 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 63 contains the trademark/trade name RPR 106541. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-64, 69-83, 87-89, 99-112 and 117-119 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hochrainer et al. (6,150,418) in view of Bartow et al. and PDR.

Hochrainer et al. (6,150,418) teaches a pharmaceutical composition comprising formoterol suitable for storage, in the form of a solution or suspension for use in inhalers, see abstract in particular. Hochrainer et al. (6,150,418) further teaches that the pharmaceutical composition is such that it can be administered by inhalation using a suitable nebuliser, see col. 4, lines 19-20 and col. 5, lines 33-41. Hochrainer et al. (6,150,418) further teaches that the pH range (preferably between 2.0-7.0 and most preferably between 4.5-5.5), the employment of inorganic acids such as phosphoric acids and the employment of buffers in its composition, see in particular col.3, lines 35-40 and col.4, line 55 to col. 5, line 7. Hochrainer et al. (6,150,418) teaches the concentration of formoterol to be between about 75 mg/ml and about 500 mg/ml, see in particular claims 1-4. It also teaches that the suspending agent is a protic liquid, a mixture of water and sodium chloride. Hochrainer et al. (6,150,418) finally teaches that additional active ingredients such as steroids could be incorporated in its composition, see claim 19.

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Hochrainer et al. (6,150,418) does not particularly teach the employment of fluticasone propionate or its concentration in its pharmaceutical composition. Neither does it teach a kit.

Bartow et al. teaches that Formoterol, a selective beta 2 adrenoceptor agonist is an effective bronchodilator. Bartow further teaches that the addition of inhaled formoterol to corticosteroid (e.g., budesonide) regimens improves lung function and reduces asthma symptoms, see pages 304 and 305.

PDR teaches fluticasone propionate as a known corticosteroid readily employed in methods of treating asthma, see flovent.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ fluticasone propionate in the composition of Hochrainer et al. (6,150,418) employed in a method of treating asthma. It would have also been obvious to include the pharmaceutical composition in a kit.

One of ordinary skill in the art would have been motivated to employ fluticasone propionate in the composition of Hochrainer et al. because both fluticasone propionate and formoterol are known to be useful in treating asthma. Combining two agents which are known to be useful to treat asthma individually into a single composition useful for the very same purpose is prima facie obvious. See *In re Kerkhoven* 205 USPQ 1069. Optimization of amounts and inclusion of a pharmaceutical composition in a kit are also within the purview of the Skilled Artisan and is therefore obvious.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mojdeh Bahar whose telephone number is (703) 305-1007. The


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examiner can normally be reached on (703) 305-1007 from 8:30 a.m. to 6:30 p.m. Monday, Tuesday, Thursday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Mojdeh Bahar
Patent Examiner
April 17, 2002


RUSSELL TRAVERS
PRIMARY EXAMINER
GROUP 1200